K131804

510(k) SUMMARY

JUL 1 2 2013

Contact Information:

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Date Prepared: June 18, 2013

Device Trade Name: Remel Xpect® Flu A&B

Predicate Device: Remel Xpect® Flu A&B (K031565; S&E July 17, 2003)

Device Classification: 21 CFR 866.3330: Influenza virus serological reagents.

Intended Use: Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.

Device Description: The Xpect® Flu A&B is a chromatographic immunoassay for the qualitative detection of influenza A and influenza B viral antigens. The test device incorporates separate membrane strips for influenza A and for influenza B. To perform the test, the patient specimen is diluted and added to the sample wells of the device. The mixture moves along the membranes by capillary action. If present, influenza A or B viral antigens in the patient sample bind anti-influenza A or B conjugated antibodies. A visible line forms as a complex of antibody-antigen-antibody coated colored particles is captured in the test region (T). Antibody coated colored particles not bound at the test line are later captured in the control region (C) containing goat anti-mouse antibody. A visible line will always appear in the control region indicating that the test is working properly. The presence of a control line combined with the absence of a visible test line is interpreted as a negative test result.

Device Comparison:

Characteristic	Remel Xpect® Flu A&B	Remel Xpect® Flu A&B
Similarities		
Intended Use	Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.	Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.
Sample	Qualitative; Influenza A and B viral antigens with differentiation.	Qualitative; Influenza A and B viral antigens with differentiation.
Test Methodology	Immunochromatographic membrane assay	Immunochromatographic membrane assay
Specimen Type	Nasal wash, nasal swab, and throat swab specimens	Nasal wash, nasal swab, and throat swab specimens
Interpretation	Visual read	Visual read
Incubation	15 minutes	15 minutes
Differences		
Analytical Sensitivity	17 influenza strains; 11 influenza A and 6 influenza B	Addition of Influenza A/Anhui/1/2013 (H7N9) to total 17 influenza strains; 11 influenza A and 6 influenza B

Summary of Performance Data:

Analytical Sensitivity:

The analytical sensitivity was evaluated using 17 influenza strains; 11 influenza A and 6 influenza B. Each viral strain was quantitated and titrated until a positive endpoint was reached using the Xpect® Flu A&B test. The amount of virus at the endpoint dilution, expressed per test, was calculated as a measure of analytical sensitivity.

Influenza Strain	Type	Detection Limit
		$TCID_{50}$/ml
A/Anhui/1/2013	A (H7N9)	1.26×10^5
A/California/04/2009	A (H1N1)	4.41×10^2
A/New Caledonia/20/1999	A (H1N1)	1.63×10^2
		$CEID_{50}$/ml
A/Puerto Rico/8/34	A (H1N1)	8.9×10^3
A/Fort Monmouth/1/47	A (H1N1)	7.9×10^1
A/New Jersey/8/76	A (H1N1)	8.9×10^1
A/Hong Kong/8/68	A (H3N2)	2.8×10^1
A/Victoria/3/75	A (H3N2)	8.9×10^2
A/Port Chalmers/1/73	A (H3N2)	4.0×10^1
A/BhGoose/QH/1/05	A (H5N1)	2.0×10^4
A/Chicken/WD/98	A (H9N2)	3.16×10^3
B/Lee/40	B	7.9×10^3
B/Allen/45	B	4×10^0
B/Maryland/1/59	B	6×10^0
B/GL/1739/54	B	8.9×10^1
B/Taiwan/2/62	B	3×10^0
B/Hong Kong/5/72	B	1.58×10^2

TCID – 50% tissue culture infectious dose; CEID – 50% chicken embryo infectious dose

Although this test has been shown to detect the influenza A/California/04/2009 (H1N1) and A/Anhui/1/3012 (H7N9) viruses cultured from positive human specimens, the performance characteristics of this device with human specimens infected with these influenza A viruses have not been established. Xpect® Flu A&B can distinguish between influenza A and B viruses, but it does not differentiate influenza subtypes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

CINDY KNAPP
DIRECTOR OF U.S. REGULATORY & GLOBAL CLINICAL AFFAIRS
REMEL INC.
12076 SANTA FE DRIVE
LENEXA KS 66215

July 12, 2013

Re: K131804
Trade/Device Name: Remel Xpect® Flu A&B
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: June 18, 2013
Received: June 19, 2013

Dear Ms. Knapp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number : k131804

Device Name: Xpect® Flu A&B

Indications For Use: Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Tamara V. Feldblyum -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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